North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner

Food Safety Modernization Act

House Committee on Food Desert Zones

March 24, 2014

Asst. Commissioner Joe Reardon

NCDA & CS

Food Safety Modernization Act

FSMA

- Signed into law January 4, 2011
- Focus on prevention and risk-based preventive controls
- Provides new enforcement authorities including authority to ensure safety of imported foods
- Directs the creation of an integrated food safety system in partnership with State and local authorities.

Why is this law necessary?

- **Globalization**
  - 1 in 6 FDA regulated food products is imported
- **Food supply more high-tech and complex**
  - More complex foods in the marketplace
  - New hazards in foods not previously seen
- **Shifting demographics**
  - Growing “at risk” population

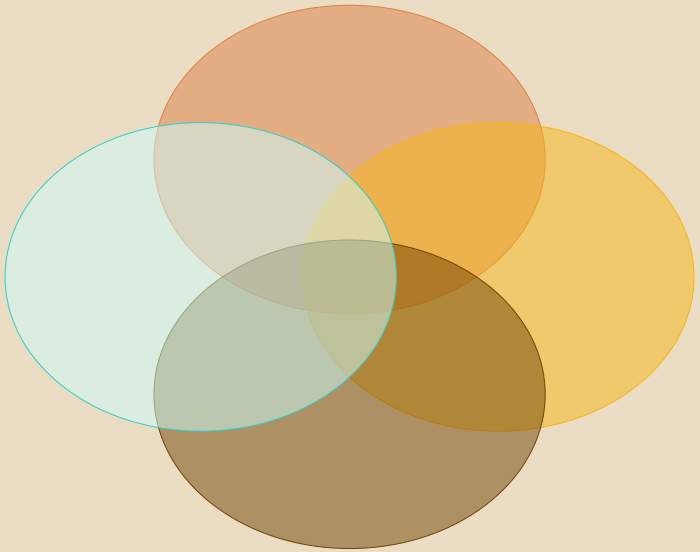
The Public Health Imperative

- **Foodborne illness is a significant burden**
  - About 48 million (1 in 6 Americans) get sick each year
  - 128,000 are hospitalized
  - 3,000 die
- Immune-compromised individuals more susceptible
- Foodborne illness is not just a stomach ache—it can cause life-long chronic disease

Main Themes of FSMA

Prevention

Enhanced Partnerships



Inspection, Compliance, and Response

Import Safety

Proposed Rules

- Produce Safety
- Preventive Controls for Human Food
- Preventive Controls for Food for Animals
- Foreign Supplier Verification Program
- Third Party Accreditation
- Intentional Adulteration
- Sanitary Transportation of food

Tester Amendment

Provides regulatory relief for small farms and facilities

- Establishes a "qualified" exemption for farms and "qualified facility" exemption for facilities based on sales:
  - Total annual sales (food) under $500,000 and;
  - Majority of sales to qualified end users (consumers) in same state or within 275 miles
- Includes provisions for modified requirements

Tester Amendment
Produce Safety Rule

- Qualified exemption for covered produce farms that meet sales requirements
- If eligible for qualified exemption, the farm must comply with modified requirements:
  - Labeling at point of sale (placard or label on product if required)
- No requirement to notify FDA of qualified status

Tester Amendment

Preventive Controls Rule

- Qualified facility exemption for very small businesses and those that meet sales requirements
- Eligible facilities must comply with modified requirements and required notification to FDA of:
  - Qualified Facility status, and;
  - Compliance with modified requirements, or
  - Compliance with non-federal regulation (state inspection) and labeling compliance

Produce Safety Rule

- Applies to farms that grow, harvest, pack or hold produce commonly consumed raw
- Science- and risk-based, considers practices and commodities:
  - Focus on routes of microbial contamination
  - Excludes produce rarely consumed raw and produce that is commercially processed
- Flexible
  - Additional time for small farms to comply
  - Variances and alternatives

Standards for Produce Safety

Focus on routes of microbial contamination

- Agricultural water
- Biological soil amendments of animal origin
- Domesticated and wild animals
- Equipment, tools, buildings and sanitation
- Worker health and hygiene
- Growing, harvesting, packing and holding activities
- Specific requirements for sprouts

Preventive Controls for Human Food Rule

- Applies risk-based preventive principles to the manufacturing, processing, packing and holding of food for humans
- Facilities, unless otherwise exempt, would be required to implement a written food safety plan that focuses on preventing hazards in foods
- Includes regulation of “on-farm mixed type” facilities
- Updated Good Manufacturing Practices

Hazard Analysis and Risk-Based Preventive Controls

- Process controls
- Food allergen controls
- Sanitation controls
- Recall plan

Preventive Controls for Food for Animals Rule

- Analogous to preventive controls rule for human food; requires risk based preventive controls
- Covers facilities that manufacture, process, pack or hold animal food, raw materials or ingredients
- Covers products such as pet food, livestock feed and human food (co-product) that is sold for use as animal food or animal food ingredient

Foreign Supplier Verification Program Rule

- Importers would be responsible for ensuring that the imported food meets FDA safety standards
- Importers required to develop, maintain, and follow an FSVP for each food imported, unless exempt
- The rule provides flexibility based type of food, size of importer, nature of hazard in food and control of hazard

Third Party Accreditation Rule

- Rule establishes a voluntary program for accrediting third-party auditors to conduct food safety audits of foreign facilities and their foods
- FDA will recognize accreditation bodies, which will in turn accredit third-party auditors under the program
- FDA can directly accredit third-party auditors in limited circumstances

Intentional Adulteration Rule

- Rule requires that domestic and foreign facilities address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm
- Requires that facilities covered under the rule develop and implement a written food defense plan that addresses significant vulnerabilities in the food operation

Sanitary Transportation of Food Rule

- Rule establishes requirements to ensure the safety of human and animal food during transportation
- This proposed rule establishes sanitation requirements for vehicles and transportation equipment, transportation operations, training, and recordkeeping
- Applies to shippers, receivers and carriers who transport food by motor or rail vehicle

Challenges

- Enormous workload
  - 7 new rules, numerous guidance documents, reports must be completed in short timeframe
- Tight deadlines
- Changes won't appear overnight
  - Building new system will be a long-range process
- Resources
  - Funding to state agencies, Land grant universities

Timeline/Next Steps

- FDA will re-release key portions of some rules for public comment in summer 2014
- Final Rules scheduled for release 2015 and 2016
- Compliance with the rules will generally begin 1 year after final rule issued; smaller facilities have additional time
- Education and Outreach:
  - Educate before Regulate

Thank You!

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